

### REMARKS

The Office Action of February 14, 2007, has been received and reviewed. Claims 1-13 and 15-19 are currently pending in the application. Claims 1-13 and 15-19 stand rejected. Claims 1, 7, 10, 12, 15, and 16 are amended herein. New claims 20 and 21 are presented herein. Basis for new claims 20 and 21 can be found through out the Specification and more specifically at original claim 15. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

#### Interview

Applicants' representatives would like to thank the Examiner for the courtesy extended during the personal interview of May 3, 2007. The interview was very in gaining an understanding of the Examiner's concerns. At the interview, the rejections made in the Office Action of February 14, 2007 were discussed as were the Examiner's and applicants perspectives with respect to the rejections. As discussed at the interview, applicants are amending the application as previously set forth in an effort to expedite prosecution. If the Office believes that further comments are necessary or desired describing the interview, the Examiner is kindly requested to contact applicants' undersigned attorney, and further detail will be promptly provided.

#### Rejections under 35 U.S.C. § 102(b)

Claim 15 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Dudler *et al.* (J. Biol. Chem. 267:9 5582-5588) (hereinafter "Dudler"). Specifically, it was asserted that "Dudler teaches an atg start codon . . . that meets the limitation of a polynucleotide sequence of claim 1." Office Action mailed February 14, 2007 at page 2. Applicants respectfully traverse the rejection as hereinafter set forth.

Applicants note that "a claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully assert that claim 15 cannot be anticipated by Dudler as Dudler does not teach each

and every element of this claim. Specifically, claim 15, as amended, recites “the polynucleotide sequence of SEQ ID NO:1.” Applicants respectfully submit that Dudler does not teach “the polynucleotide sequence of SEQ ID NO:1.” Consequently, applicants respectfully request the withdrawal of the rejection of claim 15 under 35 U.S.C. § 102(b) and reconsideration of same.

**Rejections under 35 U.S.C. § 103(a)**

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Theodoulou (Biochem. Biophys. Acta 1465 79-103) (hereinafter “Theodoulou”) in view of Dudler.

The rejection is based on the assumptions that it would have been obvious to take a plant ABC transporter gene encoding a protein having similar structural motifs to the human MRD ABC transporter and test it for inducing or enhancing production or secretion of an alkaloid such as taxol to determine the function of the plant MDR homologue. The motivation was asserted to be Theodoulou’s alleged teaching that taxol and other plant secondary metabolites are substrates of or bind MDR ABC transporter proteins and would thus be useful in bioengineering secondary product production in plants or plant cells that produce taxol or other plant secondary compounds. Since transgenic strategies for evaluating the specific function of plant ABC transporter genes were within the reach of one of ordinary skill in the art and non-plant alkaloid transporters and methods of transforming plants and maintaining plant cell cultures for the production of secondary metabolites were known in the art, one would allegedly have had a reasonable expectation of success.

Applicants respectfully traverse the rejections.

Applicants respectfully submit that there is no reasonable expectation of success in performing the present invention. Portion 5.2 of Theodoulou states that :

Examination of the ABC transporter literature suggests a range of putative functions: for example, yeast STE 6 transport peptides, mammalian MDR2 functions as a phospholipid translocator, and P-gp/MDR1 exports cytotoxic drugs from the cells and acts as a channel regulator – all these are plausible functions for P-gp homologues in plants. Moreover, the fact that plant secondary products such as vincristine and taxol are often substrates for, or inhibitors of, MDR proteins

suggests a role of plant P-gp in synthesis and compartmentation of these compounds.

Theodoulou, p. 86 (citations omitted).

Based on Theodoulou, an ordinarily skilled person interested in secondary metabolite production in plants could at best discern that ABC transporters could serve several functions, *inter alia*, an export function and possibly serving a role in the synthesis of secondary metabolites (which could result either in an increased or decreased synthesis). For instance, Theodoulou also postulates that secondary metabolites could, in fact, inhibit the action of ABC transporters. Thus, given the range of functions attributed to ABC transporters, and the fact that secondary metabolites are postulated to inhibit ABC transporters, one of ordinary skill in the art would have no reasonable expectation of success in enhancing the production or export of a secondary metabolite through the transformation of a cell with an ABC transporter.

Moreover, even if, for the sake of argument only, an ABC transporter were not inhibited by a secondary metabolite, one of ordinary skill in the art would not conclude that over-expression of the transporter would likely lead to increased production of a secondary metabolite. Given that, in many cases, secondary metabolites act as defensive compounds, one of ordinary skill in the art would expect their levels to be regulated by stress or other environmental factors, not solely on the basis of the availability of transport. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in increasing production or secretion of a secondary metabolite through the expression of an ABC transporter.

In addition, expression of genes known or thought to be involved in secondary metabolite production leads to no enhanced production or secretion of secondary metabolites. As demonstrated in the accompanying Declaration of Alain Goossens, over-expression of 20 different constructs encoding genes known or thought to be involved in secondary metabolite synthesis had no effect the level of secondary metabolites produced. Consequently, one of ordinary skill in the art would not have had a reasonable expectation of success in increasing production or secretion of a secondary metabolite through the expression of an ABC transporter.

Applicants further submit that the present invention is not obvious through the demonstration of unexpected results. Given that, as demonstrated in the Declaration of Alain

Goossens, over-expression of 20 different constructs encoding genes known or thought to be involved in secondary metabolite synthesis had no effect the level of secondary metabolites produced, one would not expect that over-expression of the levels of an ABC transporter would demonstrate such an effect. Moreover, as Theodoulou postulates that secondary metabolites might act as inhibitors of ABC transporters, one of ordinary skill in the art would find unexpected the result of ABC transporters increasing production or secretion of secondary metabolites.

For at least the foregoing reasons, applicants respectfully submit that claims 1-13 and 16-19 are patentable over the combination of Theodoulou and Dudler. As such, applicants respectfully request the withdrawal of the rejections of claims 1-13 and 16-19 under 35 U.S.C. § 103(a) and reconsideration of same.

### **CONCLUSION**

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dan J. Morath', with a stylized flourish at the end.

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DJM/djm

Enclosure: Declaration of Alain Goossens